**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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| SERIAL NO.: | 10/797,374 | GROUP ART UNIT: | 1625 |
| FILED: | March 10, 2004 | EXAMINER: | Celia C. Chang |
| TITLE: | NOVEL SUBSTITUTED BENZIMIDAZOLE DOSAGE FORMS AND METHOD OF USING SAME | | |
| DATE: | October 13, 2006 | | |

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**RESPONSE TO RESTRICTION AND ELECTION REQUIREMENT**

This communication is responsive to the Office Action dated September 13, 2006 in the above application in which a 1 month shortened statutory period for reply was set. Response to this action is timely if filed on or before October 13, 2006. No fee is believed due. If any fee is due in connection with this paper, please charge such fee (or credit any overpayment) to deposit account number 13-0019.

*IN THE CLAIMS*

This listing of claims will replace all prior versions, and listings, of claims in this application. The following amendments are without prejudice and do not constitute an admission regarding the patentability of the amended subject matter and should not be so construed.

Claims 1 – 150. (Canceled).

Claim 151. (Currently Amended) An orally deliverable pharmaceutical composition, comprising~~: at least one acid-labile substituted benzimidazole H+, K+- ATPase proton pump inhibitor~~ omeprazole in a therapeutically effective amount and ~~at least one buffering agent~~ sodium bicarbonate, wherein:

(a) the composition is in a form of a solid dosage unit; and

(b) upon oral administration of the composition to a group of subjects, the subjects exhibit an average plasma concentration of the proton pump inhibitor of at least about 0.1 μg/ml at any time within about 30 minutes after administration.

Claim 152. (Original) The composition of claim 151, wherein the dosage unit is selected from the group consisting of a tablet, a capsule, a powder, a suspension tablet, a chewable tablet, an effervescent tablet, a troche and a lozenge.

Claim 153. (Original) The composition of claim 151, wherein the dosage unit is selected from the group consisting of a chewable tablet and a capsule.

Claim 154. (Currently Amended) The composition of claim 151, wherein at least a portion of the ~~at least one proton pump inhibitor~~ omeprazole is enteric coated.

Claim 155. (Canceled)

Claim 156. (Currently Amended) The composition of claim ~~155~~ 151, wherein the ~~at least one proton pump inhibitor~~ omeprazole is present in the composition in an amount of about 1 mg to about 1000 mg.

Claim 157. (Currently Amended) The composition of claim ~~155~~ 151, wherein the ~~at least one proton pump inhibitor~~ omeprazole is present in the composition in an amount of about 5 mg to about 300 mg.

Claim 158. (Currently Amended) The composition of claim ~~155~~ 151, wherein the ~~at least one proton pump inhibitor~~ omeprazole is present in the composition in an amount of about 10 mg to about 100 mg.

Claim 159. (Currently Amended) The composition of claim ~~155~~ 151, wherein the ~~at least one proton pump inhibitor~~ omeprazole is present in the composition in an amount of about 2 mg, about 5 mg, about 10 mg, about 15 mg, about 20 mg, about 25 mg, about 30 mg, about 40 mg, about 50 mg, about 60 mg, about 65 mg, about 70 mg, about 75 mg, about 80 mg, about 85 mg, about 90 mg, about 95 mg, about 100 mg, about 105 mg, about 110mg, about 115 mg, about 120 mg, about 150 mg, about 200 mg, about 250 mg, or about 300 mg.

Claim 160. (Canceled)

Claim 161. (Canceled)

Claim 162. (Canceled)

Claim 163. (Previously Presented) The composition of claim 151, further comprising at least one pharmaceutically acceptable excipient selected from the group consisting of a carrier, a binder, a suspending agent, a flavoring agent, a sweetening agent, a disintegrant, a flow aid, a lubricant, an adjuvant, a colorant, a diluent, a moistening agent, a preservative, a parietal cell activator, an anti-foaming agent, an antioxidant, a chelating agent, an antifungal agent, an antibacterial agent, an isotonic agent, and mixtures thereof.

Claim 164. (Canceled)

Claim 165. (Currently Amended) The composition of claim 151, ~~wherein the at least one~~ further comrpising at least one additional buffering agent ~~is~~ selected from the group consisting of ~~sodium bicarbonate~~, potassium bicarbonate, magnesium hydroxide, magnesium lactate, magnesium gluconate, magnesium oxide, magnesium aluminate, magnesium carbonate, magnesium silicate, magnesium citrate, aluminum hydroxide, aluminum hydroxide/magnesium carbonate, potassium carbonate, potassium citrate, aluminum hydroxide/sodium bicarbonate coprecipitate, aluminum glycinate, aluminum magnesium hydroxide, sodium citrate, sodium tartrate, sodium acetate, sodium carbonate, sodium polyphosphate, potassium polyphosphate, sodium pyrophosphate, potassium pyrophosphate, disodium hydrogenphosphate, dipotassium hydrogenphosphate, trisodium phosphate, tripotassium phosphate, potassium metaphosphate, calcium acetate, calcium glycerophosphate, calcium hydroxide, calcium lactate, calcium carbonate, calcium gluconate, calcium bicarbonate, calcium citrate, potassium phosphate, sodium phosphate, and mixtures thereof.

Claim 166. (Currently Amended) The composition of claim 151, wherein the ~~at least one buffering agent~~ sodium bicarbonate is present in the composition in a total amount of about 1 mEq to about 200 mEq.

Claim 167. (Currently Amended) The composition of claim 151, wherein the ~~at least one buffering agent~~ sodium bicarbonate is present in the composition in a total amount of about 3 mEq to about 45 mEq.

Claim 168. (Currently Amended) The composition of claim 151, wherein the ~~at least one buffering agent~~ sodium bicarbonate is present in the composition in a total amount of about 4 mEq to about 100 mEq.

Claim 169. (Currently Amended) The composition of claim 151, wherein the ~~at least one buffering agent~~ sodium bicarbonate is present in the composition in a total amount of about 4 mEq to about 30 mEq.

Claim 170. (Currently Amended) The composition of claim 151, wherein the ~~at least one buffering agent~~ sodium bicarbonate is present in the composition in a total amount of about 10 mEq to about 70 mEq.

Claim 171. (Canceled)

Claim 172. (Currently Amended) The composition of claim ~~171~~ 151, wherein the sodium bicarbonate is present in the composition in a total amount of about 250 mg to about 4000 mg.

Claim 173. (Currently Amended) The composition of claim ~~171~~ 151, wherein the sodium bicarbonate is present in the composition in a total amount of about 1000 mg to about 1680 mg.

Claim 174. (Currently Amended) The composition of claim ~~171~~ 151, wherein the sodium bicarbonate is present in the composition in a total amount of about 7 mEq to about 25 mEq.

Claim 175. (Currently Amended) The composition of claim ~~174~~ 151, wherein the ~~at least one proton pump inhibitor is omeprazole and said~~ omeprazole is present in the composition in an amount of about 20 mg.

Claim 176. (Currently Amended) The composition of claim ~~174~~ 151, ~~wherein the at least one proton pump inhibitor is omeprazole and said~~ omeprazole is present in the composition in an amount of about 40 mg.

Claim 177. (Currently Amended) The composition of claim 151, ~~wherein the at least one buffering agent comprises~~ further comprising magnesium hydroxide.

Claim 178. (Previously Presented) The composition of claim 177, wherein the magnesium hydroxide is present in the composition in a total amount of about 12 mEq to about 24 mEq.

Claim 179. (Canceled)

Claim 180. (Currently Amended) The composition of claim 151, ~~wherein the at least one buffering agent comprises~~ further comprising calcium carbonate.

Claim 181. (Canceled)

Claim 182. (Currently Amended) The composition of claim 151, wherein at least a portion of the ~~at least one proton pump inhibitor~~ omeprazole is micronized.

Claim 183. (Previously Presented) The composition of claim 151, wherein at least a portion of the ~~at least one buffering agent~~ sodium bicarbonate is micronized.

Claim 184. (Previously Presented) The composition of claim 151, wherein the solid dosage unit is non-enteric coated.

Claim 185. (Currently Amended) The composition of claim 151, wherein upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the ~~proton pump inhibitor~~ omeprazole of at least about 0.1 μg/ml at any time within about 20 minutes after administration.

Claim 186. (Currently Amended) The composition of claim 151, wherein upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the ~~proton pump inhibitor~~ omeprazole of at least about 0.1 μg/ml at any time within about 15 minutes after administration.

Claim 187. (Currently Amended) The composition of claim 151, wherein the solid dosage unit is a chewable tablet and wherein upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the ~~proton pump inhibitor~~ omeprazole of at least about 0.1 μg/ml at any time within about 10 minutes after administration.

Claim 188. (Currently Amended) The composition of claim 151, wherein the solid dosage unit is a chewable tablet and wherein upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the

~~proton pump inhibitor~~ omeprazole of at least about 0.2 μg/ml at any time within about 15 minutes after administration.

Claim 189. (Currently Amended) The composition of claim 151, wherein upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the ~~proton pump inhibitor~~ omeprazole of at least about 0.1 μg/ml maintained from at latest about 15 minutes after administration to at earliest about 6 hours after administration.

Claim 190. (Currently Amended) The composition of claim 151, wherein upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the ~~proton pump inhibitor~~ omeprazole of at least about 0.15 μg/ml maintained from at latest about 15 minutes after administration to at earliest about 1.5 hours after administration.

Claim 191. (Currently Amended) An orally deliverable pharmaceutical composition, comprising: omeprazole or an enantiomer, isomer, tautomer, prodrug, free base, or salt thereof, in a therapeutically effective amount and ~~at least one buffering agent~~ sodium bicarbonate, wherein:

(a) the composition is in a form of a chewable tablet or capsule; and

(b) upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the ~~proton pump inhibitor~~ omeprazole of at least about 0.1 μg/ml at any time within about 30 minutes after administration.

Claim 192. (Currently Amended) The composition of claim 191, wherein upon oral administration of the composition in an omeprazole dosage amount of about 40 mg to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the ~~proton pump inhibitor~~ omeprazole of at least about 0.7 μg/ml within about 30 minutes after administration.

Claim 193. (Currently Amended) The composition of claim 191, wherein the solid dosage unit is a chewable tablet and wherein upon oral administration of the composition group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the ~~proton pump inhibitor~~ omeprazole of at least about 0.1 μg/ml at any time within about 15 minutes after administration.

Claim 194. (Currently Amended) The composition of claim 191, wherein upon oral administration of the composition in an omeprazole dosage amount of about 40 mg to a group of fasted adult human subjects, the subjects exhibit an average $C_{max}$ of the ~~proton pump inhibitor~~ omeprazole of at least about 1.0 μg/ml.

Claim 195. (Currently Amended) The composition of claim 191, wherein the solid dosage unit is a chewable tablet and wherein upon oral administration of the composition in an omeprazole dosage amount of about 40 mg to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the ~~proton pump inhibitor~~ omeprazole of at least about 0.2 μg/ml at any time within about 15 minutes after administration.

Claim 196. (Previously Presented) The composition of claim 191, wherein upon oral administration of the composition in an omeprazole dosage amount of about 40 mg to a group of fasted adult human subjects, the subjects exhibit an average $T_{max}$ of about 15 minutes to about 1 hour.

Claim 197. (Previously Presented) The composition of claim 191, wherein upon oral administration of the composition in an omeprazole dosage amount of about 40 mg to a group of fasted adult human subjects, the subjects exhibit a $T_{max}$ within about 45 minutes after administration.

Claim 198. (Previously Presented) The composition of claim 191, wherein the dosage unit is a capsule.

Claim 199. (Previously Presented) The composition of claim 191, wherein the dosage unit is a chewable tablet.

Claim 200. (Previously Presented) The composition of claim 191, further comprising at least one pharmaceutically acceptable excipient selected from the group consisting of a carrier, a binder, a suspending agent, a flavoring agent, a sweetening agent, a disintegrant, a flow aid, a lubricant, an adjuvant, a colorant, a diluent, a moistening agent, a preservative, a parietal cell activator, an anti-foaming agent, an antioxidant, a chelating agent, an antifungal agent, an antibacterial agent, an isotonic agent, and mixtures thereof.

Claim 201. (Currently Amended) The composition of claim 191, ~~wherein the at least one~~ further comprising at least one additional buffering agent ~~is~~ selected from the group consisting of calcium buffering agents, magnesium buffering agents, aluminum buffering agents, sodium

buffering agents, bicarbonate salts of a Group IA metal, alkali earth metal buffering agents, and mixtures thereof.

Claim 202. (Currently Amended) The composition of claim 191, ~~wherein the at least one~~ further comprising at least one additional buffering agent ~~is~~ selected from the group consisting of ~~sodium bicarbonate~~, potassium bicarbonate, magnesium hydroxide, magnesium lactate, magnesium gluconate, magnesium oxide, magnesium aluminate, magnesium carbonate, magnesium silicate, magnesium citrate, aluminum hydroxide, aluminum hydroxide/magnesium carbonate, potassium carbonate, potassium citrate, aluminum hydroxide/sodium bicarbonate coprecipitate, aluminum glycinate, aluminum magnesium hydroxide, sodium citrate, sodium tartrate, sodium acetate, sodium carbonate, sodium polyphosphate, potassium polyphosphate, sodium pyrophosphate, potassium pyrophosphate, disodium hydrogenphosphate, dipotassium hydrogenphosphate, trisodium phosphate, tripotassium phosphate, potassium metaphosphate, calcium acetate, calcium glycerophosphate, calcium hydroxide, calcium lactate, calcium carbonate, calcium gluconate, calcium bicarbonate, calcium citrate, potassium phosphate, sodium phosphate, and mixtures thereof.

Claim 203. (Canceled)

Claim 204. (Currently Amended) The composition of claim ~~203~~ 191, wherein the sodium bicarbonate is present in the composition in a total amount of about 250 mg to about 4000 mg.

Claim 205. (Currently Amended) The composition of claim 191, wherein the ~~at least one buffering agent~~ sodium bicarbonate is present in the composition in a total amount of about 4 mEq to about 100 mEq.

Claim 206. (Currently Amended) The composition of claim 191, wherein the ~~at least one buffering agent~~ sodium bicarbonate is present in the composition in a total amount of about 4 mEq to about 30 mEq.

Claim 207. (Currently Amended) The composition of claim 191, wherein the ~~at least one buffering agent~~ sodium bicarbonate is present in the composition in a total amount of about 10 mEq to about 70 mEq.

Claim 208. (Currently Amended) The composition of claim 191, wherein the ~~at least one buffering agent~~ sodium bicarbonate is present in the composition in a total amount of about 7 mEq and about 25 mEq.

Claim 209. (Currently Amended) The composition of claim 191, wherein the ~~at least one buffering agent~~ sodium bicarbonate is present in the composition in a total amount of about 10 mEq.

Claim 210. (Currently Amended) The composition of claim 191, wherein the ~~at least one buffering agent~~ sodium bicarbonate is present in the composition in a total amount of about 20 mEq.

Claim 211. (Currently Amended) The composition of claim 191, wherein the ~~at least one buffering agent~~ sodium bicarbonate is present in the composition in a total amount of about 40 mEq.

Claim 212. (Previously Presented) The composition of claim 191, wherein the omeprazole is present in the composition in an amount of about 20 mg.

Claim 213. (Previously Presented) The composition of claim 191, wherein the omeprazole is present in the composition in an amount of about 40 mg.

Claim 214. (Previously Presented) The composition of claim 191, wherein the omeprazole is present in the composition in an amount of about 10 mg to about 100 mg.

Claim 215. (Previously Presented) The composition of claim 151, wherein upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit an average $T_{max}$ within about 1 hour after administration.

Claim 216. (Previously Presented) The composition of claim 151, wherein upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit an average $T_{max}$ within about 30 minutes after administration.

Claim 217. (Previously Presented) The composition of claim 151, wherein upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit an average $T_{max}$ within about 45 minutes after administration.

Claim 218. (Previously Presented) The composition of claim 151, wherein upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit an average $T_{max}$ of between about 15 minutes to about 1 hour after administration.

Claim 219. (Currently Amended) The composition of claim 151, wherein upon oral administration of the composition in an omeprazole dosage amount of about 40 mg~~s~~ to a group of fasted adult human subjects, the subjects exhibit an average $C_{max}$ of the ~~proton pump inhibitor~~ omeprazole of between about 1.0 μg/ml to about 1.7 μg/ml.

Claim 220. (Currently Amended) The composition of claim 151, wherein upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit an average $C_{max}$ of the ~~proton pump inhibitor~~ omeprazole of between about 0.3 μg/ml to about 1.7 μg/ml after administration.

Claim 221. (Currently Amended) The composition of claim 151, wherein upon oral administration of the composition in an omeprazole dosage amount of 40 mg to a group of fasted adult human subjects the subjects exhibit an average $C_{max}$ of the ~~proton pump inhibitor~~ omeprazole between about 1.0 μg/ml and 1.7 μg/ml at any time within about 60 minutes after administration.

Claim 222. (Currently Amended) The composition of claim 151, wherein upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit an average $C_{max}$ of the ~~proton pump inhibitor~~ omeprazole of between about 0.3 μg/ml and 1.7 μg/ml at any time within about 60 minutes after administration.

Claim 223. (Currently Amended) The composition of claim 151, wherein the solid dosage unit is a chewable tablet and upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the ~~proton pump inhibitor~~ omeprazole of between about 0.5 μg/ml to 1.7 μg/ml at any time within about 15 minutes after administration.

Claim 224. (Currently Amended) The composition of claim 151, wherein upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the ~~proton pump inhibitor~~ omeprazole of between about 0.7 μg/ml to about 1.7 μg/ml at any time within about 30 minutes after administration.

Claim 225. (Currently Amended) The composition of claim 151, wherein upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the ~~proton pump inhibitor~~ omeprazole greater than about 1.0 μg/ml at any time within about 30 minutes after administration.

Claim 226. (Currently Amended) The composition of claim 151, wherein upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the ~~proton pump inhibitor~~ omeprazole of between about 0.3 μg/ml to 1.7 μg/ml at any time within about 30 minutes after administration.

Claim 227. (Currently Amended) The composition of claim 151, wherein upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the ~~proton pump inhibitor~~ omeprazole greater than about 1.0 μg/ml at any time within about 40 minutes after administration.

Claim 228. (Currently Amended) The composition of claim 151, wherein upon oral administration of the composition in an omeprazole dosage amount of about 40 mg~~s~~ to a group of fasted adult human subjects, the average plasma concentration of the ~~proton pump inhibitor~~ omeprazole is determined from about 10 subjects.

Claim 229. (Currently Amended) The composition of claim 151, wherein upon oral administration of the composition in an omeprazole dosage amount of about 40 mgs to a group of fasted adult human subjects, the average plasma concentration of the ~~proton pump inhibitor~~ omeprazole is determined from about 10 subjects and is between about 0.7 μg/ml and 1.7 μg/ml at any time within about 30 minutes after administration.

Claim 230. (Currently Amended) The composition of claim 151, wherein the solid dosage unit is a chewable tablet and upon oral administration of the composition to a group of fasted adult human subjects, the average plasma concentration of the ~~proton pump inhibitor~~ omeprazole is determined from about 10 subjects and is at least about 0.6 μg/ml at any time within about 15 minutes after administration.

Claim 231. (Previously Presented) The composition of claim 191, wherein upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit an average $T_{max}$ within about 45 minutes after administration.

Claim 232. (Previously Presented) The composition of claim 191, wherein upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit an average $T_{max}$ of between about 15 minutes to about 1 hour after administration.

Claim 233. (Currently Amended) The composition of claim 191, wherein upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit an average $C_{max}$ of the ~~proton pump inhibitor~~ omeprazole of between about 0.3 μg/ml and 1.7 μg/ml at any time within about 30 minutes after administration.

Claim 234. (Currently Amended) The composition of claim 191, wherein upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit

an average plasma concentration of the ~~proton pump inhibitor~~ omeprazole greater than about 1.0 μg/ml at any time within about 30 minutes after administration.

Claim 235. (Currently Amended) The composition of claim 191, wherein upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the ~~proton pump inhibitor~~ omeprazole greater than about 1.0 μg/ml at any time within about 40 minutes after administration.

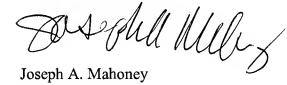
Claim 236. (Currently Amended) The composition of claim 191, wherein upon oral administration of the composition to a group of fasted adult human subjects, the average plasma concentration of the ~~proton pump inhibitor~~ omeprazole is determined from about 10 subjects.

## RESPONSE TO RESTRICTION

Applicant is filing this amendment in response to the Restriction/Election Requirement mailed on September 13, 2006. By this amendment, Applicant hereby elects the claims of Group V and omeprazole and sodium bicarbonate, without traverse. The amendments herein are made without prejudice, and Applicant reserves all of its rights to pursue any unelected subject matter in this or in a related application. In view of the species election, Applicant has amended the claims accordingly to omeprazole and sodium bicarbonate.

If, in the opinion of the Examiner, a telephone conference would help expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



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